

## Original Article

# Comparison of Acute Stent Recoil Between the Everolimus-Eluting Bioresorbable Vascular Scaffold and Two Different Drug-Eluting Metallic Stents

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## ABSTRACT

**Background:** Bioresorbable vascular scaffolds (BVS) have been developed to provide support to the vessel wall during the healing process after percutaneous coronary intervention (PCI), being resorbed afterwards. Because the scaffold is made of polymeric material, there is a concern regarding the acute recoil of the device. We compared the BVS acute recoil with that of two different metal drug-eluting stents. **Methods:** Fifty patients with non-complex lesions were included. Twenty-five of these patients were treated with a BVS who were compared to 25 patients treated with a cobalt-chromium everolimus-eluting stent (EES, n = 12) or a stainless steel biolimus-eluting stent (BES, n = 13). Acute recoil was defined as the difference between the mean diameter of the balloon during its maximum inflation pressure (X) and the mean diameter of the stent immediately after balloon deflation (Y). The percentage of acute recoil was defined as (X-Y)/X. **Results:** There was no significant difference in the baseline clinical and angiographic characteristics. Acute luminal gain was lower with BVS compared to EES and BES (1.51 ± 0.41 mm vs. 1.76 ± 0.28 mm vs. 1.9 ± 0.42 mm, P = 0.02). Acute recoil was 0.21 ± 0.13 mm vs. 0.15 ± 0.08 mm vs. 0.14 ± 0.08 mm (P = 0.21) and the percentage of acute recoil was 7.0 ± 4.6% vs. 5.0 ± 2.2% vs. 5.7 ± 4.1% (P = 0.16). **Conclusions:** BVS presented a slightly higher, although

## RESUMO

### Comparação da Retração Aguda do Stent Entre o Suporte Vascular Bioabsorvível Eluidor de Everolimus e Dois Diferentes Stents Metálicos Farmacológicos

**Introdução:** Suportes vasculares bioabsorvíveis (SVB) têm sido desenvolvidos como forma de fornecer sustentação à parede do vaso enquanto ocorre o processo de cicatrização, após a intervenção coronária percutânea (ICP), sendo absorvido posteriormente. Pelo fato da plataforma ser de material polimérico, existe preocupação em relação à retração aguda do dispositivo. Avaliamos aqui a retração aguda do SVB com a de dois diferentes stents farmacológicos metálicos. **Métodos:** Foram incluídos 50 pacientes com lesões não complexas. Dentre esses pacientes, 25 foram tratados com SVB e comparados a outros 25 pacientes tratados com stent de cromo-cobalto eluidor de everolimus (EES; n = 12) ou stent de aço inoxidável eluidor de biolimus (BES; n = 13). A retração aguda foi definida como a diferença entre o diâmetro médio do balão durante a pressão máxima de inflação (X) e o diâmetro médio do stent após o esvaziamento do balão (Y). A porcentagem de retração aguda foi definida como (X - Y)/X. **Resultados:** Não houve diferença significativa em relação às características clínicas e angiográficas basais. O ganho luminal agudo foi

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not significant, acute recoil than the two second-generation metallic drug-eluting stents.

**DESCRIPTORS:** Percutaneous coronary intervention. Drug-eluting stents. Absorbable implants. Coronary angiography.

**D**rug-eluting stents are the devices of choice for percutaneous treatment of coronary artery disease (CAD). These devices provide support to the artery walls, preventing acute and delayed retraction of the vessel, and inhibit in-stent intimal proliferation. As a consequence, the use of these devices leveraged the success rates of the procedure and allowed for the achievement of lasting results.<sup>1</sup>

However, the definitive permanence of the stents' metal rods, with the consequent imprisonment of the vessel, can cause changes in motor function and remodelling (Glagov phenomenon), leading to a poor apposition of the rods and to changes in the vessel conformability.<sup>2</sup>

In the last decade, the idea of a transitory vascular scaffold, which, for a certain period, might modulate a reparative intimal hyperplasia and, at the same time, would avoid the remodelling of the target artery, being then resorbed, has gained prominence in the area of percutaneous approach of coronary diseases. Bioresorbable vascular scaffolds (BVS), also commonly called "bioresorbable stents," would be devices that would meet these requirements. However, a major difficulty in developing such devices, especially those of polymeric composition, would be to confer sufficient radial force to prevent the occurrence of acute and delayed retraction of the vessel, not uncommon in the first prototypes.<sup>3</sup>

Among the most developed BVS clinical programs, the ABSORB® (Abbott Vascular, Santa Clara, United States), which combines a polymer platform with everolimus, an antiproliferative drug, stands out favorably. The present study aimed to compare the acute recoil of ABSORB® BVS with the observed recoil of cobalt-chromium (Xience® V; Abbott Vascular – Santa Clara, United States) and stainless steel (BioMatrix®; Biosensors International – Singapore) metal stents.

## METHODS

### Study design and target population

This was a retrospective, single-center trial, developed at the Department of Invasive Cardiology of Instituto

menor com o SVB comparado ao EES e ao BES ( $1,51 \pm 0,41$  mm vs.  $1,76 \pm 0,28$  mm vs.  $1,9 \pm 0,42$  mm;  $P = 0,02$ ). A retração aguda foi de  $0,21 \pm 0,13$  mm vs.  $0,15 \pm 0,08$  mm vs.  $0,14 \pm 0,08$  mm ( $P = 0,21$ ), e o percentual de retração aguda foi de  $7,0 \pm 4,6\%$  vs.  $5,0 \pm 2,2\%$  vs.  $5,7 \pm 4,1\%$  ( $P = 0,16$ ). **Conclusões:** O SVB demonstrou ter retração aguda ligeiramente maior, embora não significativa, que os stents metálicos farmacológicos de segunda geração.

**DESCRITORES:** Intervenção coronária percutânea. Stents farmacológicos. Implantes absorvíveis. Angiografia coronária.

Dante Pazzanese de Cardiologia, São Paulo, Brazil. The study population was composed of patients treated with ABSORB® BVS, BioMatrix®, and Xience V®, as part of local protocols developed in this institution. Some inclusion criteria were adopted in the present analysis in order to approximate the cohorts and minimize potential biases. Only patients with single *de novo* lesions between 70 and 90% (visual determination), in native coronaries with a diameter between 2.5 and 3.5 mm, were included. The maximum permitted length of the lesion was 23 mm. As a common feature for the entire group, only patients electively treated were included, and those with target lesion in left main coronary artery, ostial lesions, lesions with thrombi, lesions with excessive calcification requiring athero-ablative techniques before the device implantation, and bifurcation lesions with lateral branch > 2 mm were excluded.

### Devices used

The ABSORB® BVS has a platform composed of poly-L-lactic acid (PLLA), everolimus, an antiproliferative drug, and a delivery system. The BVS body is coated by the matrix of poly-D, L-lactic acid (PDLLA) and everolimus in a 1:1 ratio. PLLA and PDLLA are completely metabolized and absorbed by the organism.

The Xience V® stent is composed by a balloon-expandable platform MULTI-LINK VISION® with serpentine rings connected by links and manufactured from a single piece of chrome-cobalt coated with a durable polymer containing everolimus. The thickness of the rods is 0.081 µm.

The BioMatrix® stent incorporates the S-stent platform, a laser-cut stainless steel tubular stent with rods measuring 112 µm. The antiproliferative drug used is biolimus A9, a semisynthetic and highly lipophilic analogue of sirolimus. Based on *in vivo* trials, the biodegradable polymer of polylactic acid (PLA) is completely converted into lactic acid in six to nine months.

### Procedure

All procedures were performed electively, in accordance with current guidelines. The lesions were treated with

standard intervention techniques, which included mandatory pre-dilation with a shorter balloon with a diameter 0.5 mm smaller than the device used. Post-dilation, when performed (at the discretion of the operator), should have been performed with noncompliant balloons at least 30% shorter than the BVS or stent implanted.

The preprocedural dual antiplatelet therapy consisted of acetylsalicylic acid 100 to 200 mg/day and a loading dose of clopidogrel 300 mg, at least 24 hours before the procedure, or 600 mg if < 24 hours. After the intervention, acetylsalicylic acid 100 to 200 mg/day was prescribed indefinitely, and clopidogrel 75 mg/day was maintained for at least six months. During the percutaneous coronary intervention (PCI), the antithrombin therapy consisted of unfractionated heparin at a dose of 100 IU/kg (or 70 IU/kg in the case of administering glycoprotein IIb/IIIa inhibitor), aiming to achieve an activated clotting time > 250 s (or between 200 and 250 s if using glycoprotein IIb/IIIa inhibitor).

#### Quantitative coronary angiographic analysis

The pre- and post-procedural angiographies were obtained after the administration of intracoronary nitroglycerin (50 to 200 mg) in at least two corresponding orthogonal projections, which were stored in DICOM format for digital off-line analysis. The quantitative coronary angiographic (QCA) analysis was performed with a dedicated computer program, with semi-automatic lumen border detection (QAngio XA version 7.3; Medis Medical Imaging System – Leiden, the Netherlands). The qualitative and quantitative angiographic analyzes were performed by two experienced operators, following a predefined protocol. The tip of the guide catheter filled with contrast was used for calibration. The minimal lumen diameter (MLD) and the reference diameter (RD), obtained by interpolation, were used to calculate the stenosis diameter:  $SD = (1 - MLD/RD) \times 100$ . Acute recoil was defined as the difference between the mean diameter of the balloon during maximum pressure of inflation (X) and the mean intra-stent lumen diameter immediately after the deflation

of the balloon (Y); the percentage of acute recoil was defined as  $(X - Y)/X$  (Figure).

#### Statistical analysis

Categorical variables were presented as frequencies and percentages, and compared by means of an analysis of variance (ANOVA) test. Continuous variables were presented as mean and standard deviation, and compared using the nonparametric Kruskal-Wallis test. P-values < 0.05 were considered statistically significant. The statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) software version 19 for Windows (Chicago, IL).

### RESULTS

#### Clinical characteristics

The present study evaluated 50 patients undergoing elective angioplasty; 25 treated with BVS, 12 treated with EES, and other 13 with BES. The clinical characteristics are summarized in Table 1. There was no significant difference between the clinical variables analyzed, except for a higher prevalence of previous myocardial infarction in the groups treated with bare-metal stents ( $P = 0.01$ ).

#### Angiographic and procedural variables

The pre- and post-intervention angiographic variables are summarized in Table 2. The most approached vessel in the group treated with AVS was the left anterior descending artery, whereas in patients treated with metal stents the vessel most approached was the left circumflex artery ( $P = 0.24$ ). There was no significant difference between groups in relation to vessel RD ( $2.62 \pm 0.45$  mm vs.  $2.73 \pm 0.36$  mm vs.  $2.49 \pm 0.44$  mm;  $P = 0.34$ ) or length of lesions ( $11.7 \pm 4.0$  mm vs.  $3.4$  mm vs.  $10.1 \pm 12.9 \pm 5.9$  mm;  $P = 0.31$ ). The pre-procedural MLD was not different between the groups ( $0.87 \pm 0.32$  mm vs.  $0.90 \pm 0.25$  mm vs.  $0.78 \pm 0.44$  mm;  $P = 0.52$ ); after the procedure, the patients treated with BVS had lower MLD ( $2.39 \pm 0.31$  vs.  $2.66 \pm 0.26$  mm vs.  $2.69$  mm  $\pm$

TABLE 1  
Clinical characteristics

	BVS (n = 25)	EES (n = 12)	BES (n = 13)	P-value
Age, years	56.8 $\pm$ 7.0	59.8 $\pm$ 10.3	61.0 $\pm$ 4.8	0.33
Male, n (%)	15 (60)	6 (50)	9 (69.2)	0.39
Diabetes, n (%)	5 (20)	0	1 (57.7)	0.28
Hypertension, n (%)	19 (76)	9 (75)	11 (84.6)	0.82
Dyslipidemia, n (%)	19 (76)	8 (66.7)	8 (61.5)	0.66
Smoking, n (%)	3 (12)	1 (8.3)	3 (23.1)	0.57
Previous myocardial infarction, n (%)	5 (20)	7 (58.3)	8 (61.5)	0.01

BVS = bioresorbable vascular scaffold; EES = everolimus-eluting stent; BES = biolimus-eluting stent.

**TABLE 2**  
**Angiographic and procedural variables**

	<b>BVS</b> <b>(n = 25)</b>	<b>EES</b> <b>(n = 12)</b>	<b>BES</b> <b>(n = 13)</b>	<b>P value</b>
Treated vessel, n (%)				0.24
LAD	13 (52)	3 (25.0)	4 (30.8)	
LCx	4 (16)	5 (41.7)	6 (46.2)	
RCA	8 (32)	4 (33.3)	3 (23.1)	
Lesion length, mm	11.7 ± 4.0	10.1 ± 3.4	12.9 ± 5.9	0.31
Reference diameter, mm	2.62 ± 0.45	2.73 ± 0.36	2.49 ± 0.44	0.34
Stenosis diameter, %				
Pre	66.7 ± 10.5	67.7 ± 9.2	70.0 ± 13.0	0.79
Post	8.4 ± 4.0	8.2 ± 4.2	5.6 ± 2.5	0.58
Minimal luminal diameter, mm				
Pre	0.87 ± 0.32	0.90 ± 0.25	0.78 ± 0.44	0.52
Post	2.39 ± 0.31	2.66 ± 0.26	2.69 ± 0.45	0.03
Acute gain, mm	1.51 ± 0.41	1.76 ± 0.28	1.9 ± 0.42	0.02
Maximum inflation pressure of the balloon, post-dilation, atm	16.7 ± 4.0	15.0 ± 7.1	19.1 ± 3.8	0.03
Balloon:artery ratio	1.08 ± 0.14	1.05 ± 0.11	1.16 ± 0.12	0.06

LAD = left anterior descending artery; LCx = left circumflex artery; RCA = right coronary artery; BVS = bioresorbable vascular scaffold; EES = everolimus-eluting stent; BES = biolimus-eluting stent.

0.45 mm;  $P < 0.03$ ). The acute gain was lower with BVS ( $1.51 \pm 0.41$  vs.  $1.76 \pm 0.28$  mm vs.  $1.9 \pm 0.42$  mm;  $P = 0.02$ ). The maximum inflation pressure of the balloon in post-dilation was intermediate for BVS ( $16.7 \pm 4.0$  atm vs.  $15.0 \pm 7.1$  atm vs.  $19.1 \pm 3.8$  atm;  $P = 0.03$ ), as the balloon: artery ratio ( $1.08 \pm 0.14$  vs.  $1.05 \pm 0.11$  vs.  $1.16 \pm 0.12$ ;  $P = 0.06$ ).

### Evaluation of acute stent recoil

The angiographic parameters related to the evaluation of acute recoil are shown in Table 3. Acute recoil and percentage of acute recoil were numerically higher in the group treated with BVS compared with patients who received metal stents (EES and BES), but this difference did not reach statistical significance ( $0.21 \pm 0.13$  mm vs.  $0.15 \pm 0.08$  mm vs.  $0.14 \pm 0.08$  mm;  $P = 0.21$ ; and  $7.0 \pm 4.6\%$  vs.  $5.0 \pm 2.2\%$  vs.  $5.7 \pm 4.1\%$ ;  $P = 0.16$ , respectively, for BVS, EES, and BES).

### Relation of angiographic and procedural variables to the percentage of acute stent recoil

Table 4 lists the relationship of angiographic and procedural variables to the percentage of acute recoil. The balloon: artery ratio  $\geq 1.1$  presented higher percentage of acute recoil in the BVS group ( $P = 0.05$ ). The other variables were not correlated with the occurrence of acute stent recoil.

## DISCUSSION

The main finding of this study was that the ABSORB® BVS presented a slightly higher acute recoil, compared to two second-generation metal stents, although not statistically significant.

One of the benefits of metal stents is to provide an adequate vascular scaffold, preventing acute occlusion as well as acute and delayed retraction of the vessel. This property is required during the healing phase of the target segment, later making the device unnecessary. The permanent presence of a metal stent can interfere with the vessel's motor function and remodelling, and the device can permanently imprison the vessel, preventing surgical revascularization in cases where there is need to treat long segments (full metal jacket). In addition, the metal stent can imprison secondary branches and compromise the carrying out of noninvasive images of the coronary arteries, such as angiotomography and MRI.<sup>2</sup>

BVS were designed with the purpose of providing a transitional vascular scaffold in the critical healing phase after PCI and, at the same time, promoting modulation of the restorative intimal hyperplasia through the release of antiproliferative drugs. As the bioresorbable platforms are more flexible than those made of metal, there is concern whether these new devices would provide the same radial force as offered by metal platforms. Previous clinical trials that evaluated the post-implant rate

**TABLE 3**  
**Angiographic parameters related to acute stent recoil**

	BVS (n = 25)	BES (n = 13)	P-value
Diameter of the balloon at its maximum inflation pressure, mm	2.82 ± 0.32	3.09 ± 0.42	0.11
Stent diameter after balloon deflation, mm	2.60 ± 0.31	2.95 ± 0.41	0.18
Acute recoil, mm	0.21 ± 0.13	0.14 ± 0.08	0.21
Acute recoil,%	7.0 ± 4.6	5.7 ± 4.1	0.16

BVS = bioresorbable vascular scaffold; EES = everolimus-eluting stent; BES = biolimus-eluting stent.

**TABLE 4**  
**Relation of angiographic and procedural variables with percentage of acute stent recoil**

	BVS		EES		BES		P-value
	n	Recoil (%)	n	Recoil (%)	n	Recoil (%)	
RVD, mm							
≥ 3.0	6	6.6 ± 1.4	3	5.2 ± 3.9	3	3.7 ± 3.4	0.61
< 3.0	19	7.8 ± 5.2	9	4.9 ± 1.3	10	4.4 ± 2.4	0.21
P-value		> 0.99		0.60		> 0.99	
Maximum pressure, atm							
> 16	5	9.4 ± 5.8	7	5.1 ± 2.7	10	4.5 ± 2.5	0.51
≤ 16	20	7.0 ± 4.2	5	4.8 ± 1.2	3	3.2 ± 2.8	0.17
P value		0.82		0.88		0.46	
Balloon:artery ratio							
≥ 1.1	10	9.6 ± 5.3	4	5.1 ± 1.5	8	3.6 ± 2.5	0.05
< 1.1	15	6.1 ± 3.5	8	4.9 ± 2.5	5	5.2 ± 2.6	0.76
P-value		0.09		0.93		0.35	

BVS = biosorbable vascular scaffold; EES = everolimus-eluting stent; BES = biolimus-eluting stent; RVD = reference vessel diameter.

of acute recoil of non-pharmacological metal stents demonstrated a variation between 3% and 15%.<sup>4-7</sup> This wide variation in rates of acute recoil was attributed, in part, to stent material and design, and also to the difference in the definitions of acute recoil.

The idea of BVS devices is not innovative, since various types of models have been tested in experimental trials. The Igaki-Tamai stent was the first bioresorbable device tested in humans in the late 90s.<sup>8</sup> Its platform, which consisted of PLLA, had no antiproliferative drug in its composition. In this pioneering work, the rate of acute recoil was 22%, and the author used a different methodology from that employed in the present trial.

More recently published trials that used the same methodology, comparing the acute recoil of BVS with

that of second-generation metal stents, showed results similar to those of the present study. Tanimoto et al.<sup>9</sup> compared BVS with EES and found that the percentage of acute recoil was 6.9 ± 7.0% in BVS group and 4.3 ± 7.1% in EES group (P = 0.25). Onuma et al.<sup>10</sup> compared the acute recoil of two versions of ABSORB® BVS (revision 1.0 and revision 1.1) with XIENCE V® stent, and observed that the acute recoil of BVS 1.1 was slightly higher when compared to metal EES (EES: 4.3 ± 7.1%; BVS 1.0: 6.9 ± 7.0%; BVS 1.1: 6.7 ± 6.4%; P = 0.22). Recently, acute recoil data of another BVS, the DESolve, were presented, also showing good radial force and an acute recoil of 6.4 ± 4.6%.<sup>11</sup> The third BVS tested was DREAMS® (Biotronik – Bülach, Switzerland); its structure is composed of magnesium, and the antiproliferative drug used is paclitaxel. This device was assessed in the first-in-man BIOSOLVE-I



trial, demonstrating good performance with respect to acute recoil ( $9.19 \pm 7.23\%$ ).<sup>12</sup>

Since the acute recoil results from the balance between the elastic recoil of the vessel wall and the radial force of the stent, this relation may be changed by the characteristics of the lesion or by the procedure itself; for instance, the reference vessel diameter, the maximum inflation pressure of the balloon, and an oversizing of the stent used. In relation to vessel diameter and the maximum inflation pressure of the balloon, there was no difference in rates of recoil among the three groups. However, in the group of patients who had a relation balloon: artery  $\geq 1.1$ , there was a greater rate of recoil in BVS ( $P = 0.05$ ). These results highlight the importance of a properly sizing of the vessel and, possibly, preparing the injury prior to the implantation of BVS.

The present study had some limitations, since it was conducted in a single center; besides, it was a nonrandomized trial with a small number of patients. Furthermore, the results can also be related to the inclusion, in the analysis, of low complexity lesions.

## CONCLUSIONS

In this casuistry, the ABSORB® BVS demonstrated good radial force with a slightly higher, although not significant, acute recoil, compared to second generation metal stents. Studies with more patients and in more complex scenarios are needed to confirm these preliminary observations.

## CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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